Notice of Allowability	Application No.	Applicant(s)	
	10/649,068	MARK ET AL.	
	Examiner	Art Unit	
	Parikha S. Mehta	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed 19 October 2007*.

2. ☒ The allowed claim(s) is/are *1,2,4-11,14-17,19,21,23-34,36-42,50-52*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☐ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Steven R. Hansen on 26 October 2007.

The application has been amended as follows:

1. (Currently amended) A medical targeting and device introduction system, comprising:

an introducer cannula having an open distal end and an open proximal end that defines a first length, wherein the introducer cannula defines a lumen therein;

a generally linear introducer stylet that includes a distal end and a proximal end ~~that~~ which defines a second length that is substantially longer than the first length; wherein the introducer stylet is selectively and removably disposed within the lumen of the introducer cannula through the open proximal end such that the introducer stylet may be translated within the lumen such that the distal end of the introducer stylet extends outwardly from the distal end of the introducer cannula when the introducer stylet is positioned within the introducer cannula, wherein the distal end of the introducer stylet further includes a tissue piercing tip that is configured for penetrating tissue to create a pathway; and

a separate target confirmation device that is selectively insertable within the introducer cannula only when the introducer stylet is removed from the introducer cannula, wherein the target confirmation device includes a distal end that extends substantially outwardly from the distal end of the introducer cannula when the target confirmation device is engaged with the introducer cannula; and

a biopsy device that includes a handpiece, an outer cannula and an inner cannula disposed within the outer cannula;

wherein the biopsy device is configured to at least translate the inner cannula within the outer cannula and the inner cannula includes a cutting edge at its distal end,

wherein the outer cannula defines a tissue-receiving opening for receiving tissue from the target site,

wherein the cutting edge of the inner cannula cooperates with the tissue-receiving opening to sever tissue; and

wherein at least a portion of the outer cannula of the biopsy device is selectively insertable within the introducer cannula after the introducer stylet and target confirmation device are removed from the

introducer cannula.

2. (Currently Amended) The system of claim 1, wherein the introducer cannula is configured to introduce at least one of a biopsy device, a site marker, an anesthesia, a fluid, a tamponade, and a hemostatic agent.

3. (Canceled)

4. (Original) The system of claim 1, wherein the target confirmation device includes a magnetic resonance imaging (MRI) identifiable material.

5. (Currently Amended) The system of claim 4, wherein the magnetic resonance imaging (MRI) identifiable material is a band disposed proximate [[a]] the distal end of the target confirmation device so as to extend distally of the distal end of the introducer cannula.

6. (Original) The system of claim 1, wherein the system is magnetic resonance imaging (MRI) compatible.

7. (Previously Presented) A biopsy system suitable for use with a magnetic resonance imaging (MRI) device, comprising:

an introducer cannula insertable into a patient's tissue, wherein the introducer cannula includes an open distal end and an open proximal end and wherein the introducer cannula defines a first length;

an introducer stylet removably disposed within the introducer cannula and configured for tissue penetration and slidable within the introducer cannula, wherein the introducer stylet includes a distal end and a proximal end, and wherein the introducer stylet defines a second length that is substantially longer than the first length such that when the introducer stylet is fully inserted into the introducer cannula, the distal end of the introducer stylet extends through the distal end of the introducer cannula and substantially away from the distal end of the introducer cannula;

a separate target confirmation device that is selectively insertable within the introducer cannula, wherein the target confirmation device includes a distal end that extends substantially outwardly from the distal end of the introducer cannula when the target confirmation device is engaged with the introducer

cannula; wherein the target confirmation device further includes a magnetic resonance imaging (MRI) identifiable material disposed adjacent to the distal end thereof such that the material is positioned outwardly from the distal end of the introducer cannula when the target confirmation device is positioned within the introducer cannula; and

a separate biopsy device having an outer cannula and an inner cannula disposed within the outer cannula, wherein the inner cannula of the biopsy device includes a cutting edge for severing tissue and the outer cannula of the biopsy device is sized for selective insertion within the introducer cannula through the open proximal end when the introducer stylet and target confirmation device are removed from the introducer cannula.

8. (Previously Presented) The system of claim 7, wherein the introducer cannula is configured to introduce at least one of a site marker, an anesthesia, a fluid, a tamponade and a hemostatic agent into the patient.

9. (Previously Presented) The system of claim 7, wherein the distal end of the target confirmation device has a predetermined shape so as to distinguish the target confirmation device from the patient's tissue.

10. (Currently Amended) The system of claim 7, wherein the magnetic resonance imaging (MRI) identifiable material is a band disposed proximate [[a]] the distal end of the target confirmation device.

11. (Original) The system of claim 7, wherein the biopsy system is magnetic resonance imaging (MRI) compatible.

12. (Canceled)

13. (Canceled)

14. (Previously Presented) The system of claim 1, wherein the outer cannula includes a fluid conduit for delivering fluid provided in communication with the lumen.

15. (Original) The system of claim 14, wherein the fluid conduit includes a directional valve.

16. (Previously Presented) The system of claim 1, wherein the target confirmation device includes a proximal end having a first fitting interface that engages and connects to a second fitting interface on the introducer cannula upon insertion of the target confirmation device into the introducer cannula so as to prevent relative movement between the target confirmation device and the introducer cannula.

17. (Currently Amended) The system of claim 1, wherein the ~~outer~~ introducer cannula includes a ~~haemostatic~~ hemostatic valve.

18. (Canceled)

19. (Previously Presented) The system of claim 1, wherein the target confirmation device includes a relatively low artifact generating material sufficient to permit the material to be readily identified under magnetic resonance imaging (MRI).

20. (Canceled)

21. (Currently Amended) The system of claim 1 [[20]], wherein the target confirmation device has a proximal end, and the distance between [[a]] the proximal end and [[a]] the distal end of the target confirmation device is approximately equal to the distance between the center of the tissue receiving opening of the outer cannula ~~cutting element~~ and the handpiece of the biopsy device.

22. (Canceled)

23. (Previously Presented) The system of claim 5, wherein the distance between a proximal end of the target confirmation device and the targeting band is approximately equal to the distance between the center of the tissue receiving opening and the handpiece of the biopsy device.

24. (Currently Amended) The system of claim 1 [[20]], wherein the length of the ~~cutting~~

~~element~~ outer cannula is approximately equal to the length of the introducer stylet.

25. (Currently Amended) The system of claim 1 [[20]], wherein the length of the target confirmation device is approximately equal to the length of the introducer stylet.

26. (Currently Amended) A medical procedure, comprising:

inserting an introducer stylet into an outer cannula such that a distal end of the introducer stylet extends substantially outwardly from a distal end of the outer cannula;

inserting the introducer stylet, with the outer cannula disposed thereon, into a patient's body, thereby creating a pathway to a target tissue;

removing the introducer stylet from the patient's body, but leaving behind the outer cannula; and inserting a separate target confirmation device into the patient's body through the outer cannula such that a distal end of the target confirmation device extends substantially outwardly from [[a]] the distal end of the outer cannula and confirming the location of the target tissue relative to the target confirmation device.

27. (Original) The method of claim 26, further including the step of providing an image of the target tissue prior to or contemporaneous with inserting the introducer stylet into the patient's body.

28. (Original) The method of claim 26, further including the step of providing an image of the target confirmation device within the patient's body.

29. (Original) The method of claim 26, further including the step of removing the target confirmation device and inserting a biopsy device through the outer cannula to a position adjacent the target tissue.

30. (Original) The method of claim 29, further including the step of performing a biopsy of the target tissue.

31. (Original) The method of claim 30, further including the step of aspirating a biopsy site formed after removing the target tissue.

32. (Original) The method of claim 31, further including the step of inserting a medical treatment into the biopsy site through the outer cannula.

33. (Currently Amended) The system of claim 1, ~~further including a tissue resection device including a tissue receiving opening positioned in a sidewall of the tissue resection device adjacent a distal end thereof,~~ wherein said tissue receiving opening is rotatable relative to said introducer cannula.

34. (Currently Amended) The system of claim 7, wherein said biopsy device including a tissue receiving opening positioned in a sidewall of the outer cannula adjacent a distal end thereof, wherein said tissue receiving opening is rotatable relative to said introducer cannula.

35. (Canceled)

36. (Previously Presented) The system of claim 1, wherein the target confirmation device is a low artifact generating material.

37. (Previously Presented) The system of claim 1, wherein the target confirmation device provides a low artifact.

38. (Previously Presented) The system of claim 1, wherein the target confirmation device is a signal void generating material.

39. (Previously Presented) The system of claim 1, wherein the target confirmation device provides a signal void.

40. (Currently Amended) The system of claim 1 [[20]], wherein the length of the target confirmation device is approximately equal to the length of the outer cannula ~~cutting element~~.

41. (Original) The method of claim 26, further including the step of providing an image of the target tissue after inserting the introducer stylet into the patient's body.

42. (Currently Amended) The method of claim 26, further including removing the target confirmation device and inserting a biopsy device including a tissue receiving opening[[,]] into the outer cannula, wherein said tissue receiving opening is selectively rotatable relative to said outer cannula.

43. (Canceled)

44. (Canceled)

45. (Canceled)

46. (Canceled)

47. (Canceled)

48. (Canceled)

49. (Canceled)

50. (Currently Amended) The system of claim 7, wherein ~~the biopsy device includes an outer cannula and an inner cannula disposed in the outer cannula, wherein the inner cannula has a cutting element disposed on a distal end thereof and~~ the outer cannula has a tissue receiving opening.

51. (Currently Amended) A breast biopsy system for use with a magnetic resonance imaging (MRI) device, comprising:

a first introducer cannula insertable into a patient's breast tissue, wherein the first introducer cannula has a single lumen and defines an open distal end and an open proximal end;

[[an]] a unitary introducer and target confirmation stylet that is slidable in a distal direction into and along the single lumen of the first introducer cannula and which is slidably removable therefrom in a proximal direction, wherein the introducer and target confirmation stylet includes a distal end having a piercing tip configured for breast tissue penetration and a proximal end, and wherein at least a portion of the piercing tip of the introducer and target confirmation stylet extends in the distal direction through and beyond the distal end of the first introducer cannula into a first relative position between the first

introducer cannula and the introducer and target confirmation stylet ~~in which at least a portion of the piercing tip of the introducer and target confirmation device extends in the distal direction beyond the open proximal end of the first outer cannula~~;

wherein at least one of the first introducer cannula and the introducer and target confirmation stylet includes a magnetic resonance imaging (MRI) compatible material that is visible under MRI imaging; and

a breast tissue biopsy device that is slidably insertable in the distal direction within the single lumen of the first introducer cannula through the open proximal end only after the introducer and target confirmation stylet is removed ~~from the first introducer cannula~~ in the proximal direction from the first introducer cannula, wherein the biopsy device comprises a handpiece, a second outer cannula and a third inner cutting cannula, and wherein the third inner cutting cannula is rotatable and translatable within the second outer cannula and the second outer cannula has a tissue receiving opening, the third inner cutting cannula has a lumen, and the lumen of the third inner cutting cannula selectively communicates with the tissue receiving opening to excise tissue adjacent the tissue receiving opening of the second outer cannula when the second outer cannula is inserted into a patient's breast tissue.

52. (Currently Amended) A medical procedure, comprising:

locating a target tissue area in a patient's breast using a magnetic resonance imaging (MRI) system;

providing a unitary introducer and target confirmation stylet ~~constructed of MRI~~ having a tissue piercing tip at a distal end thereof and comprising a magnetic resonance imaging compatible material;

inserting the introducer and target confirmation stylet through [[an]] a first introducer cannula having an open distal end such that the piercing tip of the introducer and target confirmation stylet extends at least partially through the open distal end of the first introducer cannula;

inserting the introducer and target confirmation stylet with the first introducer cannula disposed thereon, into a patient's body such that the tissue piercing tip of the introducer and target confirmation stylet enters the patient's breast prior to the distal end of the first introducer cannula and moving the introducer and target confirmation stylet with the first introducer cannula thereon through the patient's breast tissue to create a pathway to a target tissue;

imaging at least a distal end of the introducer and target confirmation stylet while the introducer and target confirmation ~~deivce~~ device is positioned within the patient's breast to confirm the location of the introducer and target confirmation stylet relative to the target tissue;

slidably removing the introducer and target confirmation stylet from the patient's breast, thereby leaving behind the first introducer cannula such that the distal end of the first introducer cannula remains positioned within the patient's breast;

providing a biopsy device comprising a handpiece, a second outer cannula, and a third inner cutting cannula, wherein the second outer cannula has a proximal end and a distal end, the proximal end of the second outer cannula ~~being~~ is located proximal the handpiece, and the tissue receiving opening is located adjacent the distal end of the second outer cannula, and wherein the third inner cutting cannula has a proximal end, a distal end, a cutting edge formed on the distal end, a lumen, and is selectively rotatable and translatable within the second outer cannula such that the tissue receiving opening of the second outer cannula selectively communicates with the lumen of the third inner cutting cannula;

inserting the second outer cannula of the biopsy device within the first introducer cannula such that the tissue receiving opening of the second outer cannula extends through the open distal end of the first introducer cannula when the introducer and target confirmation stylet is removed from the first introducer cannula; and

positioning the tissue receiving opening of the second outer cannula in a selected relative position with respect to the target tissue to allow a portion of the target breast tissue to prolapse into the tissue receiving opening; moving the third inner cutting cannula distally within the second outer cannula while rotating the third inner cutting cannula relative to the second outer cannula until the cutting edge extends beyond the tissue receiving opening, thereby cutting a portion of the breast tissue that has prolapsed into the tissue receiving opening.

2. The following is an examiner's statement of reasons for allowance: the prior art of record fails to teach or fairly suggest a method and/or system for excisional biopsy wherein the cannula is configured to accommodate only one of the guidewire ('target confirmation device' as recited in the claims) and stylet at a given time.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha S. Mehta whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Parikha Solanki Mehta
Examiner – Art Unit 3737